UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte PETER NASH,
DONALD L. ROBINSON as legal representative of
JOHN W. ROSEVEAR (deceased),
and DONALD L. ROBINSON

Appeal 2006-2575
Application 10/025,567[1]
Technology Center 1600

ON BRIEF

Before ADAMS, GRIMES, and LINCK, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to compositions for inhibiting the adherence of harmful microorganisms in the intestinal tracts of food animals. The examiner has rejected the claims as

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[1] This is a divisional application of Serial No. 09/616,843, which is pending before us as Appeal No. 2006-3378.

being nonenabled, lacking written description, having new matter, and obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm-in-part.

BACKGROUND

The bacteria *Peptostreptococcus anaerobius*, *Clostridium aminophilum*, and *Clostridium sticklandii*, are among organisms "responsible for wasting up to 25 percent of the protein in cattle diets. This is a loss of as much as $25 billion annually to cattle producers . . . ." (Specification 1.)

The Specification discloses that these organisms act by degrading protein consumed by the host to ammonia. (*Id.*) The ammonia is then "converted to urea by the liver and kidneys and thus lost to the host when excreted as urine. These deleterious organisms also compete with beneficial organisms which the host needs for the efficient utilization of ammonia." (*Id.* at 1-2.)

Antibodies to these bacteria can be produced by inoculating female birds with a bacterial immunogen, and then harvesting the eggs from the inoculated birds. (*Id.* at 5-6.) "The total antibody-containing contents of the eggs are [then] separated from the shells and dried." (*Id.* at 6.) The dried antibody-containing egg material may be mixed with animal feed. (*Id.*)

The Specification discloses that orally administering the dried antibody-containing egg preparations will inhibit the "ability of colony-forming protein-wasting organisms, such as *P. anaerobius*, *C. sticklandii* and *C. aminophilum*, and colony forming disease-causing organisms, such as *E. coli 0157:H7*, *Listeria*, *Salmonella* and *Campylobacter*, to adhere in the

rumen or intestinal tracts of food animals and thus reduce their ability to multiply, grow and colonize." (*Id.* at 7 (emphasis omitted).)

DISCUSSION

1. CLAIMS

Claims 1, 3, 5-7, and 12-29 are pending and on appeal. Appellants separate the claims into two groups for argument. (Br. 11.) Group I consists of claims 1, 3, 5, 13, 16, and 19, and Group II consists of claims 6, 7, 12, 14, 15, 17, 18, and 20-29. (*Id.* at 11-12.)

Claims 1, 5, 6, and 13 are representative, and read as follows:

1. A microbial adherence inhibitor for administration to food animals to inhibit the adherence of a targeted colony-forming immunogen in the rumen or intestinal tracts of said food animals produced by the method of:

A. Inoculating female chickens, in or about to reach their egg laying age, with a particular target colony-forming immunogen;

B. Allowing a period of time sufficient to permit the production in the chickens of antibody to the target colony-forming immunogen, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the chickens;

D. Separating the entire contents of said harvested eggs from the shells; and

E. Drying said separated entire contents of said eggs, said dried entire contents of said eggs when administered to food animals with animal feed promoting the growth of the food animals by decreasing the waste of dietary protein caused by the presence of a colony-forming immunogen in the rumen or intestinal tracts of the food animals by binding the IgY immunoglobulins to the colony-forming immunogen, said binding of the IgY immunoglobulins to the colony-forming immunogen being assisted by the IgM and IgA immunoglobulins to inhibit the ability of the protein-wasting immunogen to adhere to the rumen or intestinal tracts of the animals.

5. A microbial adherence inhibitor for administration to a living being to inhibit the adherence of a colony-forming immunogen in the digestive tract of the living being, said colony-forming immunogen is from the class consisting of *E. coli*, *Listeria*, *Salmonella* and *Campylobacter* produced by the method of:

A. Inoculating female birds in or about to reach their egg laying age with the colony-forming immunogen;

B. Allowing a period of time sufficient to permit the production in the birds of antibody to the colony-forming immunogen, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the birds;

D. Separating the entire contents of said harvested eggs from the shells; and

E. Drying said separated entire contents of said eggs, said dried entire contents of said eggs when administered to the living being inhibiting the adherence of the colony-forming immunogen in the digestive tract by binding the IgY immunoglobulins to the colony-forming immunogen, said binding of the IgY immunoglobulins to the colony-forming immunogen being assisted by the IgM and IgA immunoglobulins.

6. A microbial adherence inhibitor for administration to food animals to inhibit the adherence of a targeted colony-forming immunogen in the rumen or intestinal tracts of said food animals produced by the method of:

A. Inoculating female chickens, in or about to reach their egg laying age, with a particular target colony-forming immunogen;

B. Allowing a period of time sufficient to permit the production in the chickens of antibody to the target colony-forming immunogen, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the chickens;

D. Separating the entire contents of said harvested eggs from the shells;

E. Providing a dry feed carrier material; and

F. Coating said dry feed carrier material with the separated

entire contents of said harvested eggs, said dry food carrier material coated with the entire contents of said eggs when administered to the food animals inhibiting the adherence of colony-forming immunogen in the digestive tract by binding the IgY immunoglobulins to the colony-forming immunogen, said binding of the IgY immunoglobulins to the colony-forming immunogen being assisted by the IgM and IgA immunoglobulins.

13. A microbial adherence inhibitor for promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of said food animals by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the immunogen to multiply, said protein-wasting immunogen is P antigen from *P. anaerobius* produced by the method of:

A. Inoculating female birds, in or about to reach their egg laying age, with P antigen from *P. anaerobius*;

B. Allowing a period of time sufficient to permit the production in the bird and eggs laid by the birds of antibody to P antigen from *P. anaerobius*, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the birds;

D. Separating the antibody-containing contents of said eggs from the shells; and

E. Drying said entire contents of said eggs, said dried entire contents of said eggs when administered to food animals with animal feed promoting the growth of the food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of the food animals by binding the IgY immunoglobulins to the protein-wasting immunogen, said binding of the IgY immunoglobulins to the protein-wasting immunogen being assisted by the IgM and IgA immunoglobulins to inhibit the ability of the protein-wasting immunogen to adhere to the rumen or intestinal tracts of the animals.

Claim 1 is a product-by-process claim directed to a composition containing antibodies to a microorganism that forms colonies in the digestive tract of a food animal. The composition is made by inoculating

chickens with an immunogen from a microorganism that colonizes the digestive tract of food animals, waiting for the chickens to produce antibodies to the organism in their eggs, harvesting the eggs, separating the entire contents of the eggs from the shells, and drying the contents of the eggs.

Claim 1 also states that the antibody-containing dried egg composition, "when administered to food animals," promotes the growth of the animals by decreasing the waste of protein; that the IgY in the administered composition binds to the microorganism in the food animal's digestive tract; and that the IgM and IgA in the composition assists in the binding of the IgY to the microorganism.

Claim 1 is directed to a product, not a process. As stated in *Texas Instruments Inc. v. U.S. Intern. Trade Comm'n*, 988 F.2d 1165, 1172, 26 USPQ2d 1018, 1023 (Fed. Cir. 1993), "[a] 'whereby' clause that merely states the result of the limitations in the claim adds nothing to the patentability or substance of the claim." While the word "whereby" does not appear in claim 1, the recitations regarding the effect of the composition "when administered" do not affect the structure, form, or ingredients of the composition. Therefore, other than confirming the presence of the IgY, IgM, and IgA antibodies in the composition, we do not interpret claim 1's intended result recitations to place any positive limitations on the claim.

The preamble of claim 1 recites that the composition is "for administration to food animals to inhibit the adherence of a targeted colony-forming immunogen in the rumen or intestinal tracts of said food animals." Because the body of claim 1 recites a structurally complete composition, we

do not interpret the preamble's intended use recitation as placing any limitations on the claimed composition. *See Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997) ("Where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation.").

Thus, overall, we interpret claim 1 as encompassing a composition comprising the dried non-shell components of chicken eggs which contain IgY, IgA, and IgM antibodies to microorganisms that cause the host to waste dietary protein.

Claim 5 is similar to claim 1 but requires that the composition contain antibodies to the bacterial species *E. coli* or a member of the bacterial genera Listeria, Salmonella, or Campylobacter. Therefore, overall, we interpret claim 5 as encompassing a composition comprising the dried non-shell components of bird eggs which contain IgY, IgA, and IgM antibodies to *E. coli*, Listeria, Salmonella, or Campylobacter.

Claim 6 is similar to claim 1 but contains the additional requirement that the composition is prepared by coating the antibody-containing non-shell portion of the eggs onto a dry feed carrier material. We therefore interpret claim 6 as encompassing a composition comprising the dried non-shell components of chicken eggs which contain IgY, IgA, and IgM antibodies to microorganisms that adhere to the digestive tract of a host animal, the antibody-containing egg composition having been coated on to a dry feed carrier material.

Claim 13 is similar to claim 1 but requires the antibodies in the composition to be prepared by inoculating female birds with P antigen from *P. anaerobius*. We interpret claim 13 to be directed to a composition produced by inoculating with isolated P antigen, as opposed to whole *P. anaerobius* cells. This interpretation is supported by the language of claim 13 itself, which requires inoculating with "P antigen from *P. anaerobius*," i.e., P antigen derived from *P. anaerobius* cells.

This claim interpretation is also supported by the prosecution history. When originally filed, as now, claim 13 recited inoculating with P antigen from *P. anaerobius*. The Examiner rejected claim 13 as nonenabled. Office action mailed June 3, 2003, page 2.

In response, Appellants argued that the

> target protein wasting immunogen is from a class consisting of *P. anaerobius*, *C. sticklandii* and *C. aminophilium* [sic]. These immunogens are described in Examples 7, 8 and 9 on pages 17 and 18 of the specification. Examples 17, 18 and 19 relate to these immunogens.

Response filed October 23, 2003, page 17.

The specification's Example 7 (pages 16-17) describes isolation of P antigen from *P. anaerobius* cells, and Example 17 (pages 21-22) describes inoculation of chickens with isolated P antigen. Thus, the examples that Appellants pointed to describe inoculation of chickens with isolated P antigen. Appellants' characterization of the claimed method is consistent with our interpretation that claim 13 requires inoculating with isolated P antigen.

The Specification discloses that P antigen can be prepared by culturing *P. anaerobius* in broth, recovering the culture by low speed centrifugation, removing whole cells by centrifugation, and recovering the P antigen as the supernatant from the separated whole cells. (Specification 16.)

Claims 16 and 19 recite essentially the same compositions as claim 13. However, instead of antibodies to P antigen from *P. anaerobius*, claims 16 and 19 require the compositions to contain antibodies to CS antigen from *Clostridium sticklandii* and CA antigen from *Clostridium aminophilum*, respectively. As with claim 13, we interpret claims 16 and 19 to be limited to methods comprising inoculating with isolated CS and CA antigen, respectively.

The Specification discloses that these antigens can be prepared by culturing *C. sticklandii* or *C. aminophilum* in broth, recovering the culture by low speed centrifugation, removing whole cells by centrifugation, and recovering the CS or CA antigen as the supernatant from the separated whole cells. (Specification 17-18.) Thus, we interpret claims 13, 16, and 19 as encompassing compositions comprising the dried non-shell components of bird eggs which contain IgY, IgA, and IgM antibodies to isolated antigens separated from whole cells in culture by, for example, centrifugation.

2. SCOPE OF ENABLEMENT

Claims 1, 3, 5-7, and 12-29 stand rejected under 35 U.S.C. § 112, first paragraph, as enabling only "a microbial adherence inhibitor in the form of IgY for administration to food animals to inhibit the adherence of targeted colony-forming bacteria in the rumen or intestinal tracts of said food animal wherein the colony-forming bacteria are selected from the group consisting

of *P. anaerobius*, *C. sticklandii*, *C. aminophilium*[sic], *E. Coli* [sic], *Listeria*, *Salmonella* and *Campylobacter* . . . ." (Answer 5.)

The Examiner notes that the Specification "discloses only five microbial adherence inhibitors," whereas the claim term "'immunogen' could be peptide, protein, bacteria, virus, or parasite." (*Id.* at 5-6). The examiner summarizes the rationale for the enablement rejection as follows:

> Given the indefinite number of undisclosed colony-forming immunogen[s], it is unpredictable which undisclosed microbial inhibitor in the form of chicken antibody IgY including IgA and IgM in the albumin would bind specifically to said undisclosed colony-forming immunogen, in turn, would be useful for inhibiting the adherence of any protein wasting immunogen in the food animals or any living being. Given the indefinite number of undisclosed microbial adherence inhibitor[s], there is no in vivo working example demonstrating that the claimed microbial adherence inhibitor is effective for inhibiting the adherence of all colony-forming immunogen (bacteria, parasites, virus, etc[.]) . . . in the rumen or intestinal tracts of food animal.

(*Id.* at 7.)

Appellants argue that the Specification describes the steps required to make and use the claimed compositions, including the preparation of immunogens, immunization of chickens, preparation of the dried antibody-containing composition from the harvested eggs, and feeding the composition to cattle. (Br. 15-16.) Appellants also point out that claims 3, 5, 12, and 24-29 are limited to compositions targeted to specific organisms, and "do not include all targeted colony-forming immunogens." (*Id.* at 16.)

Appellants argue that the specification provides "a representative number of species of colony-forming protein-wasting immunogens to

describe the genus identified by the terms target colony-forming immunogen," and that "[t]hese immunogens are well known protein-wasting immunogens." (*Id.*) Appellants urge that the exemplified organisms are "sufficient to identify a genus of like immunogens to a person skilled in the art," and that Stolle[2] would have made the skilled artisan aware of deleterious bacteria. (*Id.*)

The Examiner bears the burden of establishing that practicing the full scope of the claimed subject matter would have required undue experimentation. *In re Wright*, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) ("[T]he PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application.") .

While the specification must enable the skilled artisan to practice the full scope of the claimed subject matter, the specification need not "necessarily describe how to make and use every possible variant of the claimed invention, for the artisan's knowledge of the prior art and routine experimentation can often fill gaps, interpolate between embodiments, and perhaps even extrapolate beyond the disclosed embodiments, depending upon the predictability of the art." *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244, 68 USPQ2d 1280, 1287 (Fed. Cir. 2003) (citation omitted).

We agree with Appellants that the Examiner has not established that practicing the full scope of the claims would have required undue

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[2]Stolle et al., U.S. Patent 4,748,018, issued May 31, 1988.

experimentation. The Specification (page 1) discloses that protein-wasting microorganisms were known in the art, and that degrading protein within the digestive tract to ammonia is one mechanism by which the organisms waste dietary protein. The Krause[3] reference, cited by the Examiner in the obviousness rejections, also discusses protein wasting in food animals by ammonia production. (Krause 815, left col.) As argued by Appellants, Stolle provides an extensive list of digestive tract pathogens to which antibodies can be raised in chickens. (Stolle, col. 5, ll. 1-35.)

Thus, one skilled in the art would have known the identities and properties of protein-wasting organisms and other undesirable digestive tract organisms. In our view, given this knowledge, the experimentation required to identify colony-forming immunogens would not have been undue. We therefore do not agree with the Examiner (Answer 26) that the Specification provides "inadequate guidance as to the structure of the 'colony-forming immunogen.'"

The Examiner may be correct that the structure and binding of proteins to antibodies is highly sensitive to small changes in amino acid sequences. Nonetheless, a number of prior art references of record demonstrate that antibodies produced from chicken eggs can effectively bind to targeted microorganisms in the digestive tract. For example, Tokoro,[4]

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[3] Krause et al., "An rRNA Approach for Assessing the Role of Obligate Amino Acid-Fermenting Bacteria in Ruminal Amino Acid Deamination," *Applied and Environmental Microbiology*, Vol. 62, No. 3, pp. 815-821 (1996).

[4] Tokoro, U.S. Patent, 5,080,895, issued January 14, 1992.

Stolle, and Yokoyama[5] disclose the preparation, from chicken eggs, of antibodies having binding specificity sufficient to inhibit targeted microorganisms in the digestive tract. (Tokoro, col. 12, l. 4, through col. 14, l. 17; Stolle, col. 6, ll. 38-46; Yokoyama 388, abstract.) The prior art of record therefore demonstrates that effective antibodies can be produced in the manner recited in the claims without undue experimentation.

We agree with Appellants that the Examiner has not shown that undue experimentation would have been required to practice the full scope of the claimed subject matter. We therefore reverse the enablement rejection of claims 1, 3, 5-7 and 12-29.

3. WRITTEN DESCRIPTION

Claims 1, 3, 5-7, and 12-29 stand rejected under 35 U.S.C. § 112, first paragraph, "as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention." (Answer 7.)

The Examiner urges that the claim term "immunogen" encompasses peptide or protein antigens for which no amino acid structure has been provided. (*Id.* at 8.) The Examiner also urges that "[g]iven the infinite number of undisclosed colony-forming immunogen[s], the said undisclosed colony[-]forming immunogen has not been adequately described. Since the immunogen is not adequately described, the binding specificity of microbial

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[5] Yokoyama et al., "Oral passive immunization against experimental salmonellosis in mice using chicken egg yolk antibodies specific for *Salmonella enteritidis* and *S. typhimurium*," *Vaccine*, Vol. 16, No. 4, pp. 388-393 (1998).

adherence inhibitor in the form of IgY including IgA and IgM to that undisclosed immunogen is not adequately described." (*Id.*)

The Examiner concludes that because the Specification describes IgY-containing microbial inhibitor only from birds inoculated with *P. anaerobius*, *C. sticklandii*, *C. aminophilum*, *E. coli* serogroup 0157: H7, Salmonella, and Campylobacter, "one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species of colony-forming immunogens [and], in turn, the microbial inhibitor to said undisclosed colony-forming immunogens. Thus, Applicant was not in possession of the claimed genus." (*Id.*)

Appellants respond to the written description rejection by reiterating their arguments regarding the enablement rejection. (Br. 17.) Appellants also argue that the Specification explains how the IgY, IgA, and IgM from chickens' eggs bind tightly to the adherins of invading microorganisms to prevent the microorganisms from adhering to the digestive tract of the host organisms, and how the albumin from the eggs protects the antibodies' binding activity. (*Id.* at 17-18.)

We will reverse this rejection. We first note that it is unclear why the Examiner included claims 3, 5, 12-21, and 24-29 in this ground of rejection. Rather than reciting a broad genus, these claims recite compositions targeted to the exact microorganisms conceded by the Examiner as being described. (Answer 8 ("Other [than] the specific microbial adherence inhibitor in the form of IgY that inhibits the specific colony forming bacteria *P. anaerobius*, *C. sticklandii*, *C. aminophilium*, *E*[.] *coli*, *Listeria*, [and] *Salmonella* from adhering to the rumen or digestive track of food animal, there is inadequate

written description about the microbial adherence inhibitor . . . .").) Thus, the rejection of these claims appears to be inconsistent with the Examiner's own reasoning.

Turning to the remaining claims, the written description requirement obliges an applicant to "convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991).

The Federal Circuit has cautioned that generic claims involving immune responses are not invalid for lack of written description merely because "success is not assured." *Capon v. Eshhar*, 418 F.3d 1349, 1360, 76 USPQ2d 1078, 1086 (Fed. Cir. 2005). Rather, in evaluating whether the specification provides an adequate written description for generic claims to biological subject matter, one must look to "a variety of factors, such as the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, the predictability of the aspect at issue, and other considerations appropriate to the subject matter." *Id.* at 1359, 76 USPQ2d at 1085.

Thus, "[i]t is not necessary that every permutation within a generally operable invention be effective in order for an inventor to obtain a generic claim, provided that the effect is sufficiently demonstrated to characterize a generic invention." *Id.*

In concluding that the Specification does not demonstrate possession of the claimed subject matter, the Examiner has not, in our view, sufficiently

considered the state of the art. As discussed *supra*, both the Specification and Krause teach that protein-wasting microorganisms were known in the art, and that one route of protein loss is the microorganisms' conversion of protein to ammonia in the host's digestive tract. (Specification 1; Krause 815, left col.)

As also discussed *supra*, Stolle provides an extensive list of digestive tract pathogens to which antibodies can be raised in chickens. (Stolle, col. 5, ll. 1-35.) Tokoro and Yokoyama also disclose the preparation, from chicken eggs, of antibodies having binding specificity sufficient to inhibit targeted microorganisms within the digestive tract. (Tokoro, col. 12, l. 4, through col. 14, l. 17; Yokoyama 388, abstract.) Sugita-Konishi[6] also produced, in chicken eggs, antibody capable of inhibiting pathogenic digestive tract bacteria. (Sugita-Konishi 886.)

Therefore, the Specification and prior art provide the properties and identities of protein-wasting and colony-forming organisms to which antibodies can be raised. Given the knowledge in the art, we do not agree with the Examiner that the Specification fails to demonstrate possession of the generic claims. Rather, when the Specification is properly viewed alongside the knowledge in the prior art, one of skill would have recognized that Appellants were in possession of the full scope of the claimed subject matter. We therefore reverse the written description rejection of claims 1, 3, 5-7, and 12-29.

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[6] Sugita-Konishi et al., "Immune Functions of Immunoglobulin Y Isolated from Egg Yolk of Hens Immunized with Various Infectious Bacteria," *Biosci. Biotech. Biochem.*, Vol. 60, No. 5, pp. 886-888 (1996).

4. NEW MATTER

Claims 5 and 12 stand rejected under 35 U.S.C. § 112, first paragraph, as containing new matter. (Answer 9.)

The Examiner argues that the term "'living being' in Claims 5 and 12 represents a departure from the Specification and the claims as originally filed. The passages pointed out by applicant in the amendment filed 10/23/03 do not provide a clear support for the said phrase." (*Id.*)

Appellants argue that "[t]he specification describes the microbial adherence inhibitor used for food animals and hosts to inhibit adherence of colony-forming immunogens in the rumen and intestinal tracts," and that the generic term "host" is present in the Specification. (Br. 18.)

We will reverse this rejection. As discussed *supra*, we do not interpret claim 5's preamble recitation, "for administration to a living being to inhibit the adherence of a colony-forming immunogen in the digestive tract of the living being," as placing any limitation on claim 5, because the body of the claim recites a structurally complete composition. *Rowe v. Dror*, 112 F.3d at 478, 42 USPQ2d at 1553.

As also discussed *supra*, we interpret the intended result recitation in the body of claim 5, regarding the composition's effect "when administered to the living being," as not placing a positive limitation on the claim. Thus, because it does not affect any portion of the claim having patentable weight, the amendment of claim 5 to recite "living being" does not change the scope of the claim. Because the amendment does not change the scope of the claim, the amendment does not add new matter to the claim. This analysis applies equally to claim 12. The rejection of claims 5 and 12 is reversed.

5. OBVIOUSNESS OF CLAIMS 1, 3, 5, 13, 16, and 19

Claims 1, 3, 5, 13, 16, and 19 stand rejected under 35 U.S.C. § 103(a) as being obvious over Tokoro, Kaspers,[7] Pimentel,[8] and Krause. (Answer 9.)

As an initial matter, we note that the Examiner's reliance on the abstract of the Kaspers article, rather than the full text, is contrary to established Office-approved practice. The Memorandum from Stephen Kunin, Deputy Commissioner for Patent Examination Policy, dated April 29, 2002 (copy attached), states that, except in circumstances not applicable here, no appeal with a rejection relying on an abstract should be forwarded when the underlying article qualifies as prior art. *See also* MPEP § 706.02 ("Citation of and reliance upon an abstract without citation of and reliance upon the underlying scientific document is generally inappropriate where both the abstract and the underlying document are prior art.").

However, the full text of the Kaspers article was cited to Appellants on February 13, 2004, in related Application Serial No. 10/038,260, according to its official Image File Wrapper. Appellants therefore had notice of the contents of the Kaspers article before they filed their Appeal Brief. Appellants do not allege that the Examiner's interpretation of the abstract is inconsistent with the full text of the article. We therefore do not consider the Examiner's failure to cite the full article to be prejudicial to Appellants, and see no reason to remand the application.

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[7] Kaspers et al. "Transfer of IgA from Albumen into the Yolk sac during Embryonic Development in the Chicken," *J. Vet. Med. A*, Vol. 43, pp. 225-231 (1996).
[8] Pimentel, U.S. Patent 5,741,489, issued April 21, 1998.

The Examiner cites Tokoro as preparing antibodies to pathogenic *E. coli* strains in chicken eggs, separating the yolk and albumin from the shell, drying the antibody-containing egg preparation to form a powder product, and adding the product to livestock food. (Answer 9-10.) The Examiner relies on Kaspers to establish that "IgG (IgY) is [the] primary immunoglobulin isotype from the egg yolk[,] while IgM and IgA are mainly found in the albumin." (*Id.* at 10.)

The Examiner cites Pimentel as teaching that "whole egg (white and yolk) antibody can be dried and mixed with feed without first isolating the antibodies from the yolk," and that "antibodies have been reported to be more resistant to degradation by gastric acidity when [] contained in the spray-dried whole egg as compared to purified spray[]-dried antibodies." (*Id.* at 10-11.)

The Examiner cites Krause as disclosing that *P. anaerobius*, *C. aminophilum*, and *C. sticklandii* cause nutrition depletion in livestock, thereby decreasing growth. (*Id.* at 11.)

The Examiner concludes that it would have been obvious to substitute *P. anaerobius*, *C. aminophilum*, and *C. sticklandii* for the *E. coli* strains of Tokoro to produce eggs containing antibodies to the protein wasting organisms. (*Id.*) As motivation for the substitution, the Examiner cites Tokoro's disclosure of the simplicity, efficiency, and low cost of making egg antibody, Pimentel's disclosure that whole egg preparations of antibodies resist gastric degradation, and Krause's disclosure that *P. anaerobius*, *C. aminophilum*, and *C. sticklandii* cause growth-inhibiting nutrition depletion in livestock. (*Id.*)

We agree with the Examiner that these teachings would have made claims 1, 3, and 5 obvious to one of ordinary skill.

Claim 5 is representative of claims 1, 3, and 5. As discussed *supra*, we interpret claim 5 to encompass a composition comprising the dried non-shell components of a bird egg which contains IgY, IgA, and IgM antibodies to *E. coli*, Listeria, Salmonella or Campylobacter.

Tokoro describes (col. 4, l. 67, through col. 5, l. 6) the production of antibodies in chickens to a number of pathogenic *E. coli* strains, "includ[ing] those coliform bacteria or factors which cause colibacillosis, particularly diarrhea such as 'scour' in young animals such as piglets or calves. Specific examples of such bacteria or factors are porcine ETEC (enterotoxigenic E. coli) . . . ."

Tokoro also discloses that "[i]n a preferred embodiment of the production method of an antibody-containing substance, the yolk, albumen, or *overall ovum* of an egg of an immunized hen is simply dried to form a powder after homogenization to yield the desired product without fractionation such as ultrafiltration." (Col. 8, ll. 14-19 (emphasis added).) Tokoro uses "overall ovum" to refer to the yolk and albumin separated from the egg shells. (*See* col. 6, ll. 17-18.)

Tokoro therefore describes a composition containing antibodies to *E. coli*, one of the organisms recited in claim 5. The composition is prepared by inoculating a female bird, obtaining antibodies in the non-shell portion of the birds' eggs, and drying the resulting composition. (Tokoro, col. 5, l. 29, through col. 6, l. 27.) The composition is therefore prepared using the exact steps recited in claim 5. Because Tokoro's composition is obtained exactly

as claimed, Tokoro's composition necessarily contains the IgY, IgM, and IgA recited in claim 5. By itself, Tokoro therefore describes all of the limitations in claim 5.

"It is well settled that a claim is anticipated if each and every limitation is found either expressly or inherently in a single prior art reference." *Celeritas Techs. Ltd. v. Rockwell Int'l Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522 (Fed. Cir. 1998). Because "anticipation is the epitome of obviousness," *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548, 220 USPQ 193, 198 (Fed. Cir. 1983), we agree with the Examiner that claim 5 would have been obvious in view of the cited references.

Appellants argue that "[t]here is no disclosure in Tokoro '895 of an IgY immunoglobulin that binds to a colony-forming immunogen." (Br. 23-24.) We do not agree.

"Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claims limitations, it anticipates." *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349, 64 USPQ2d 1202, 1206 (Fed. Cir. 2002). As discussed *supra*, Tokoro describes inoculating chickens with pathogenic *E. coli* strains. Claim 5 clearly states that *E. coli* is a "colony-forming immunogen." As also discussed *supra*, one of Tokoro's preferred embodiments is the composition prepared by simply separating the antibody-containing yolk and albumin from the egg shells, and drying the composition, the exact steps recited in claim 5. Because it is made using the exact steps recited in claim 5, Tokoro's preferred composition necessarily contains the IgY, IgM, and IgA antibodies recited in the claim.

Appellants argue that Kaspers, Pimentel, and Krause do not individually teach various claim limitations. (Br. 24-25.)

We do not find Appellants' argument persuasive. First, the Examiner relies on the combined teachings of the references, and it is well settled that "[n]on-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references." *In re Merck & Co.*, 800 F.2d 1091, 1097, 231 USPQ 375, 380 (Fed. Cir. 1986). In addition, Tokoro discloses all of the limitations of claim 5, and claims 1, 3, and 5 stand or fall together.

Appellants argue that

> there are no motivating directions or suggestions in these references that would impel one skilled in the art to produce *the claimed method.* There is no teaching *of a method* of promoting the growth of food animals by binding IgY immunoglobulins combined with IgM and IgA immunoglobulins to protein-wasting immunogens to inhibit the ability of the protein-wasting immunogens to adhere to the rumen or intestinal tracts of food animals.

(Br. 25-26 (emphasis added).)

We are not persuaded by Appellants' argument. All of the pending claims are directed to products, not processes. Thus, claim 5 does not require a step of binding antibodies to a microorganism. Rather, claim 5 recites a dried composition comprising the non-shell portions of an egg that contains IgY, IgA, and IgM antibodies to *E. coli*, Listeria, Salmonella, or Campylobacter. Tokoro describes such a composition.

Thus, we agree with the Examiner that claim 5 would have been obvious to one of ordinary skill at the time of the invention. Claims 1 and 3

fall with claim 5 because Appellants do not argue them separately. We therefore affirm the rejection of claims 1, 3, and 5 over Tokoro, Kaspers, Pimentel, and Krause.

Claims 13, 16, and 19 stand on a different footing, however. As discussed *supra*, we interpret these claims to require immunization with bacterial antigens that have been separated from whole cells in culture by, for example, centrifugation.

We agree with the Examiner that, because Krause identifies *P. anaerobius*, *C. sticklandii*, and *C. aminophilum* as causing the waste of dietary protein in food animals, the reference suggests inoculating birds with cells of these organisms, so as to produce antibodies to the organisms in the birds' eggs.

However, we do not see, and the Examiner does not point to, any evidence suggesting that those skilled in the art would have found it obvious to separate the cells of these organism from the culture supernatant, and inoculate birds with the antigen-containing culture supernatant rather than the cells. Nor has the Examiner shown that the cited references would have provided a reasonable expectation that inoculating birds with the culture supernatant of *P. anaerobius*, *C. sticklandii*, or *C. aminophilum* (or P, CS, or CA antigens isolated by any other method) would have yielded antibodies capable of inhibiting the organism in the digestive tracts of food animals.

Thus, in our view, the Examiner has not established that one of ordinary skill would have been motivated to inoculate birds with isolated P, CS, or CA antigen, with a reasonable expectation that doing so would have

successfully produced antibody capable of inhibiting *P. anaerobius*, *C. sticklandii*, or *C. aminophilum*.

Because the Examiner has not adequately demonstrated how the references suggest all of the limitations in claims 13, 16, and 19, we reverse the obviousness rejection of those claims.

To summarize, Tokoro describes a composition encompassed by representative claim 5. We therefore affirm the obviousness rejection of claims 1, 3, and 5. However, because the cited references do not teach or suggest preparing a dried avian egg composition containing antibodies to isolated P, CS, or CA antigens, we reverse the obviousness rejection of claims 13, 16, and 19.

6. OBVIOUSNESS OF CLAIMS 14, 15, 17, 18, 20, AND 21

Claims 14, 15, 17, 18, 20, and 21 stand rejected under 35 U.S.C. § 103(a) as being obvious in view of Tokoro, Kaspers, Pimentel, and Krause, as applied to claims 1, 3, 5, 13, 16, and 19, and further in view of Adalsteinsson[9] and Betz.[10] (Answer 11-13.)

We reverse this rejection.

Claims 14, 15, 17, 18, 20, and 21 all ultimately depend from claim 13, 16, or 19. As discussed *supra*, claims 13, 16, and 19 recite compositions comprising antibodies to isolated P antigen, CS antigen, or CA antigen. As also discussed *supra*, the Examiner has not shown that Tokoro, Kaspers, Pimentel, and Krause would have suggested a composition containing antibodies to those antigens. We see nothing in Adalsteinsson, Betz, or the

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[9] Adalsteinsson et al., U.S. Patent 6,086,878, issued July 11, 2000.
[10] Betz et al., U.S. Patent 4,166,867, issued September 4, 1979.

Examiner's reasoning that remedies the deficiencies of Tokoro, Kaspers, Pimentel, and Krause. We therefore reverse the obviousness rejection of claims 14, 15, 17, 18, 20, and 21.

7. OBVIOUSNESS OF CLAIM 5

Claim 5 also stands rejected under 35 U.S.C. § 103(a) as being obvious in view of Tokoro, Kaspers, Pimentel, Stolle, Sugita-Konishi, and Yokoyama. (Answer 13.)

As we understand it, the basis of this rejection is that the non-*E. coli* embodiments of claim 5 would have been obvious based on the cited references. However, for the reasons discussed *supra*, we conclude that Tokoro anticipates claim 5. We therefore agree with the Examiner that claim 5 is unpatentable over the cited references, regardless of whether the references would have suggested the Listeria, Salmonella, or Campylobacter embodiments of the claim.

In response to this rejection, Appellants reiterate their previous arguments regarding Tokoro, Kaspers, and Pimentel. (Br. 28.) These arguments are addressed above. Appellants also argue that Stolle, Sugita-Konishi, and Yokoyama do not disclose binding IgY, IgM, and IgA with protein-wasting organisms in the digestive tract or that the binding of IgY to organisms is assisted by IgM and IgA. (*Id.* at 29-30.) Appellants further argue that the evidence of record would not have motivated one of skill to combine the references. (*Id.* at 30.)

We do not find these arguments persuasive. Again, Tokoro discloses, expressly or inherently, a method encompassed by claim 5. Therefore, the teachings of Stolle, Sugita-Konishi, and Yokoyama, as well as the

combinability of those references, are all irrelevant to the patentability of claim 5.

We therefore affirm the Examiner's rejection of claim 5 over Tokoro, Kaspers, Pimentel, Stolle, Sugita-Konishi, and Yokoyama.

8. OBVIOUSNESS OF CLAIMS 6, 7, 12, 22, AND 23

Claim 6, 7, 12, 22, and 23 stand rejected under 35 U.S.C. § 103(a) as being obvious over Tokoro, Kaspers, Pimentel, Stolle, Sugita-Konishi, Yokoyama, Adalsteinsson, and Betz. (Answer 16.)

As discussed *supra*, Tokoro teaches preparing dried whole avian egg compositions containing antibodies to pathogenic digestive tract microorganisms, including *E. coli*. The Examiner concedes that Tokoro does not disclose coating the antibody-containing composition onto feed carrier materials as recited in claim 6. (Answer 17.)

To meet this deficiency, the Examiner cites Adalsteinsson as disclosing that "hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or sprayed to coat directly onto carrier[s] such as food pellets to maintain[] antibody titers sufficient to increase muscle protein and reduce fat in subject animal[s]." (*Id.* at 19.)

Appellants argue that these claims require that "[t]he separated entire contents of the harvested eggs are not dried before they are coated onto the dry feed carrier material. This avoids the reduction of the effectiveness of the IgY, IgM, and IgA immunoglobulins caused by the process of drying the entire contents of the harvested eggs." (Br. 31.) Appellants further argue that the Examiner has failed to show any clear and particular motivation for combining Tokoro with the other references.

We do not find Appellants' argument persuasive.

Claim 6 is representative of these claims. As discussed *supra*, we interpret claim 6 as encompassing a composition comprising the dried non-shell components of chicken eggs which contain IgY, IgA, and IgM antibodies to microorganisms which adhere to the digestive tract of a host animal, the antibody-containing egg composition having been coated on to a dry feed carrier material.

Contrary to Appellants' argument, claim 6 does not require the claimed composition to be produced by a process in which the contents of the harvested eggs are not dried before they are coated on to the feed carrier. Claim 6 recites the steps of separating the contents of the harvested eggs, providing a dry feed carrier material, and then coating the feed carrier material with the contents of the eggs. Claim 6 does not contain any language limiting the claim to the positively recited steps.

Adalsteinsson describes a composition comprising an orally administered chicken egg-derived antibody that binds a gastrointestinal neuro-modulator, such as cholecystokinin. (Col. 4, l. 58, through col. 5, l. 10.) Adalsteinsson teaches that the composition can be made by "drying the egg into an egg powder . . . [which] can be mixed with food animal feed rations or sprayed directly onto food pellets preferably in oil and thus fed directly to food animals in a simple fashion." (Col. 9, ll. 29-38.)

Thus, one of ordinary skill, applying Tokoro's teachings to make orally administered dried whole egg compositions comprising antibodies to microorganisms harmful to food animals, would have recognized from Adalsteinsson the desirability of coating antibody-containing dried egg

powder intended for oral administration onto feed pellets. We therefore agree with the Examiner that one of ordinary skill would have been motivated by Adalsteinsson to coat Tokoro's compositions onto a feed carrier, as recited in claim 6.

We affirm the obviousness rejection of claim 6. Claims 7, 12, 22, and 23 fall with claim 6.

9. OBVIOUSNESS OF CLAIMS 24-29

Claims 24-29 stand rejected under 35 U.S.C. § 103(a) as being obvious over Tokoro, Kaspers, Pimentel, Stolle, Krause, Adalsteinsson, and Betz. (Answer 20.)

We reverse this rejection.

Claims 24-29 all recite compositions comprising antibodies raised by inoculating with isolated P antigen, CS antigen, or CA antigen. As discussed *supra* with respect to claims 13-21, the Examiner has not shown, and we do not see, where Tokoro, Kaspers, Pimentel, Krause, Adalsteinsson, and Betz, alone or in combination, suggest a composition containing antibodies to isolated P, CS, or CA antigen. We see nothing in Stolle, or the Examiner's reasoning, that remedies the deficiencies of Tokoro, Kaspers, Pimentel, Krause, Adalsteinsson, and Betz.

We therefore reverse the obviousness rejection of claims 24-29.

SUMMARY

We reverse the written description and enablement rejections of claims 1, 3, 5-7, and 12-29.

We reverse the new matter rejection of claims 5 and 12.

We affirm the obviousness rejections of claims 1, 3, 5-7, 12, 22, and 23.

We reverse the obvious rejections of claims 13-21 and 24-29.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a)(1)(iv)(2006).

AFFIRMED-IN-PART

Donald E. Adams)
Administrative Patent Judge)
)
)
Eric Grimes) BOARD OF PATENT
Administrative Patent Judge) APPEALS AND
)
Nancy J. Linck) INTERFERENCES
Administrative Patent Judge)

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UNITED STATES
PATENT AND
TRADEMARK OFFICE

Commissioner for Patents
Washington, DC 20231
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Memorandum

DATE: April 29, 2002

TO: Technology Center Directors
Patent Examining Corps

FROM: Stephen G. Kunin
Deputy Commissioner for Patent Examination Policy

SUBJECT: Reliance upon abstracts and foreign language documents in support of a rejection

Effective immediately, no appeal should be forwarded to the Board of Patent Appeals and Interferences for decision where: (1) a rejection is supported in whole or part by an abstract without reference to the underlying document, except in those rare situations where the abstract qualifies as prior art but the underlying document does not (or is non-existent); or (2) a rejection is supported in whole or part by a prior art document not in the English language, unless accompanied by a translation of the prior art document into English. An example of a situation where the abstract qualifies as prior art but the underlying document does not is as follows:

- An "abstract" describing certain subject matter, which is the subject of a not-yet completed scientific paper, is prepared and publicly distributed on a date in advance of an event at which the rest of the subject matter in the scientific paper is to be unveiled. In the course of time, the event occurs and the subject matter in the scientific paper is made public by publication of the scientific paper. In this instance, as to an application under examination, the difference in publication dates could make the abstract prior art as a printed publication and the scientific paper not prior art as a printed publication.

Evidence uncovered in searching the claimed subject matter of a patent application often includes English language abstracts of underlying documents, such as technical literature or foreign patent documents which may not be in the English language. When an abstract is used to support a rejection, the evidence relied upon is the facts contained in the abstract, not additional facts that may be contained in the underlying full text document.

Citation of and reliance upon an abstract without citation of and reliance upon the underlying scientific document is generally inappropriate where both the abstract and the underlying document are prior art. See *Ex parte Jones*, 62 USPQ2d 1206, 1208 (Bd. Pat. App. & Inter. 2001) (unpublished).

To determine whether both the abstract and the underlying document are prior art, a copy of the underlying document must be obtained and analyzed. If the document is in a language other than English and the examiner seeks to rely on that document, a translation must be obtained so that the record is clear as to the precise facts the examiner is relying upon in support of the rejection. The record must also be clear as to whether the examiner is relying upon the abstract or the full text document to support a rejection.

The rationale for this is several-fold. It is not uncommon for a full text document to reveal that the document fully anticipates an invention that the abstract renders obvious at best. The converse may also be true, that the full text document will include teachings away from the invention that will preclude an obviousness rejection under 35 U.S.C. 103, when the abstract alone appears to support the rejection. An abstract can have a different effective publication date than the full text document. Because all patentability determinations are fact dependent, obtaining and considering full text documents at the earliest practicable time in the examination process will yield the fullest available set of facts upon which to determine patentability, thereby improving quality and reducing pendency.

When both the abstract and the underlying document qualify as prior art, the underlying document should normally be used to support a rejection. In limited circumstances, it may be appropriate for the examiner to make a rejection in a non-final Office action based in whole or in part on the abstract only without relying on the full text document. In such circumstances, the full text document and a translation (if not in English) may be supplied in the next Office action. Whether the next Office action may be made final is governed by MPEP 706.07(a).

Experience at the Board of Patent Appeals and Interferences indicates that consideration of an English language version of the underlying document instead of the abstract aids in the resolution of the patentability issues raised in an appeal. Many cases would not have gone to appeal had the examiner obtained the full text of the underlying document and any needed translation and considered the patentability of the claims in light of the fuller set of facts.

All participants in an appeal conference should review the appealed rejections to ensure that if an abstract is relied upon as evidence to support the rejection, the full text document and any needed translation has been obtained and considered. It should be a rare occurrence that an Examiner's Answer is prepared where a rejection is based upon an abstract rather than the underlying document. The record needs to make clear that efforts to obtain the underlying document were unsuccessful (e.g., because there is no underlying document or the date of the underlying document does not qualify as prior art). Under those circumstances, the abstract will constitute the best evidence available and the patentability issues will have to be resolved on the facts described in the abstract.